Section 5- 510(k) Summary

JUN 18 2013

Submitter: St Jude Medical, NMD
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Establishment Registration Number: 1627487

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Date Prepared: March 18, 2013

Trade Name: Multi Lead Trial Cable

Classification Name: Stimulator, Spinal Cord, Implanted (Pain Relief) 84GZB

Classification: Class II – 21 CFR 882.5880

Product Code: GZB

Predicate Device: The subject device is equivalent to the ANS Trial Cable (K070847 cleared on April 11, 2007)

Device Description: The Multi Lead Trial Cable (MLTC) consists of a case, a cable and a HDMI connector, and is used to electromechanically connect an implantable lead to an SJM trial stimulation system. The MLTC case has two cavities in which implantable lead(s) can be inserted and locked/unlocked in place via a slider mechanism. The extension cable provides extra length, so the cable can reach from the operative sterile field over the top of the anesthesia screen for the intraoperative trial procedure. The RJ45-HDMI adapter contains HDMI connectors at one end and RJ45 connectors at the other end. Since the MLTC uses a micro-HDMI connector and the SJM trial stimulation system uses a RJ45 connector, the adapter enables the Multi Lead Trial Cable to connect to the Trial Stimulator (MTS).

Intended Use: The multilead trial cable is intended to be used as an accessory with compatible St. Jude Medical trial stimulator systems for trial stimulation either intraoperatively or postoperatively for a maximum of 30 days. The RJ45 adapter is intended to connect the multilead trial cable to compatible trial stimulators.

Indications for Use: SJM trial stimulation systems are indicated for the treatment of chronic pain of the trunk and limbs, either as the sole mitigating

agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

Summary of Technological Characteristics of the New Device Compared to the Predicate Device:

The Multi Lead Trial Cable has the same intended use as the predicate device. The operating principle of the subject device and the predicate device is to pass electrical current from the trial stimulator to the lead. All technological characteristics of the MLTC are substantially equivalent to the predicate device including biocompatibility, sterilization, and labeling. Where differences exist between the subject device and the predicate device, performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the subject device.

Non-Clinical Test Summary:

Completion of all verification and validation activities demonstrated that the subject devices meet their predetermined design and performance specifications. The testing included mechanical, electrical, biocompatibility, sterilization and shelf life testing to confirm that the minor differences in the design and materials used do not adversely affect the safety and effectiveness of the subject device.

Conclusion:

St. Jude Medical considers the Multi Lead Trial Cable to be substantially equivalent to the predicate device listed above. This conclusion is based upon the device similarities in design, technological characteristics, principle of operation, indications for use and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2013

St. Jude Medical
c/o Ms. Lakshmi Padmanabhan
Regulatory Affairs Specialist
6901 Preston Road
Plano, TX 75024

Re: K130545
Trade/Device Name: Multi Lead Trial Cable
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZB, GZF
Dated: March 20, 2013
Received: March 21, 2013

Dear Ms. Padmanabhan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K130545

Device Name: Multi Lead Trial Cable

Indications For Use:

SJM trial stimulation systems are indicated for the treatment of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

The multilead trial cable is intended to be used as an accessory with compatible St. Jude Medical trial stimulator systems for trial stimulation either intraoperatively or postoperatively for a maximum of 30 days. The RJ45 adapter is intended to connect the multilead trial cable to compatible trial stimulators.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K130545